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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Bowen-Leaver, et al.

Serial No.: 09/897,871

Group Art Unit: 1619

Filed: July 2, 2001

Examiner: Yu, Gina C.

For: Ringing Nanogel Compositions

RESPONSE PURSUANT TO 37 CFR 1.111 AND 1.115

Remarks

§112 Rejection second paragraph

The Examiner rejects Claims 1 to 3, 5 to 11, 15 and 16 under 35 U.S.C. §112, second paragraph, as being indefinite. Specifically, the Examiner finds the term "silicone component" to be vague and indefinite because the term is further defined to comprise at least one volatile silicone oil. The "silicone component" can be according to Applicants' assertion a volatile silicone oil itself or a mixture with other volatile and/or nonvolatile silicone oils. Further, the Examiner notes that the Office policy is to interpret the claim language as broadly as possible. In response to this, Applicants note that while the policy of the Office is understood with respect to broad interpretation, the breadth of the interpretation is not unlimited. Rather, the interpretation is limited by the definition of the term either known in the art to one of ordinary skill or as it is defined by Applicants in the specification. Thus, in broadly interpreting the term "silicone component" the Office is limited by the definition given to the term.

In the present specification, the term "silicone component" is defined at page 8, paragraph [00023] wherein it states "The silicone component comprises at least one volatile silicone oil." There are no silicones other than oils provided in the definition of the silicone component. However, to make certain there is no possible other interpretation of this term, Applicants amend the term to be "silicone oil component." Support for this amendment is found in the aforementioned page and paragraph of the specification. Thus, Applicants request that this rejection be withdrawn.

§103 Rejection

Claims 1 to 3, 5 and 6 are rejected under 35 U.S.C. §103 as being unpatentable over U.S. Patent No. 6,120,778, "the Simonnet reference." in view of U.S. Patent No. 4,026,818, "the Claudelli reference"

and U.S. Patent Application No. 2002/0034489 A1, "the Wiegland reference". Pursuant to 35 U.S.C. §103, a *prima facie* case of obviousness requires, *inter alia*, establishing that prior art reference(s) teach or suggest all of the claim limitations. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). To establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. *In re Kotzab*, 55 USPQ2d 1313, 1316 (CAFC 2000); see *In re Dance*, 160 F.3d 1339, 1343, 48 USPQ2d 1635, 1637 (Fed. Cir. 1998); *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). The combination of references cited by the Examiner fail to teach or suggest a combined oil phase and silicone component that is at least 5 times the emulsifier. This is a claim limitation in the present invention and therefore the claims of the present invention are nonobvious.

None of the cited references, alone or in combination, teaches or suggests an oil-in-water nanogel having an oil phase and silicone component that is at least 5 times the amount of the emulsifier as the claims of the present invention are amended. The present invention contains an oil phase and a silicone component that are self-structured such that the resulting ringing nanogel has a difference in complex viscosity of at least about 10,000 poise under oscillation stress in the range of about 0 to 5,000 (dyne/cm^2). The nanogels of the present invention upon application to the skin feel pleasantly smooth at first and then transitions to a wet-like feel that is refreshing on the skin. However, because the composition is a gel, the consistency is not thin and drippy like water, and it is not tacky like other gels. This feeling and consistency is surprising especially since it is achieved with a low level of emulsifiers in comparison with the oil phase and the silicone component. This is not taught or suggested by the cited references.

The Simonnet reference, the primary reference, teaches transparent oil in water nanoemulsions but fails to teach a "ringing" gel. According to the Examiner, the Simonnet reference teaches an oily phase that may be mineral oils or volatile or nonvolatile silicone oils. The oily phase may be 5 to 40 percent by weight of the emulsion as taught at column 3, lines 33 to 35. However, the Simonnet reference fails to teach or suggest a separate oil phase from that of the silicone oil component, like that of the present invention, and therefore, the Simonnet reference, alone fails to teach the present invention. Further, the Simonnet reference fails to teach or suggest the combination of the oil phase and silicone component that is 5 times the emulsifier. And for a second reason, the Simonnet reference fails by itself to teach or suggest the present invention. Furthermore, it fails in combination with the other secondary references, the Weigland and the Claudelli references, to teach or suggest the missing element of the

claimed invention, namely the combination of the oil phase and the silicone component that is 5 times the emulsifier.

It is the Examiner's contention in the present office action that the combination of the Simonnet reference with the Claudelli and Wiegland references would have been obvious to one of ordinary skill in the art because of an expectation to successfully produce a transparent gel composition having a large amount of oil with enhanced penetration of actives into the skin. However, there is no reference to where in the cited references such an expectation is based. Further, while the classification of the amount of oil by the Examiner is "large", the amount of oil in combination with The Claudelli reference, as the Examiner points out in the Office Action of December 5, 2001, fails to teach or suggest a silicone component, and therefore, alone fails to teach or suggest the nanogels of the present invention. The "difference in complex viscosity" is viewed by the Examiner as being an obvious variation of the prior art. However, the combination of the references fails to teach or suggest an oil phase and silicone component that is 5 times the amount of the emulsifier. In each of the Examples of the Wiegland reference, the amount of the oil in the oil phase, which can include a silicone, is less than the amount of the surfactant in the surfactant phase. Thus, it is clear that the oil phase and the silicone component in for example, Example 5 of the Wiegland reference, are not 5 times the emulsifier. Therefore, the Wiegland reference alone fails to teach or suggest the present invention. In combination, these references fail to remedy the defect of the Simonnet reference.

The combination of the Claudelli and the Simonnet references, like the individual references themselves, fails to teach or suggest the present invention. Neither reference teaches or suggests a combination of an oil phase and a silicone component that is greater than at least about 20 percent of the composition, and that is at least about 5 times the amount of the emulsifier in the composition. To start, there is no motivation in either reference that would lead one of ordinary skill in the art to make a nanoemulsion having a separate oil phase and a separate silicone component. Next, there is no teaching or suggestion in either reference to make a nanoemulsion that contains the high amounts of the oil phase and the silicone component in comparison with the emulsifier in the composition. The examples in the Simonnet reference have between 4.5 and 5.0 percent silicone surfactant, and the oil phase is between 12 and 15 percent. Thus, the oil phase is only to about 2.4 (12/5) to 3.3 (15/4.5) times the surfactant. Therefore, the Simonnet reference, like the Wiegland reference, fails to teach or suggest the present invention having an oil phase, including the silicone component, that is at least about 5 times the emulsifier. Similarly, this is not taught or suggested by the Claudelli reference which does not even

mention a silicone comp nent. Thus, it can be seen that the combination of Simonnet, Wiegland and Claudelli references fails to teach or suggest the present invention.

The Examiner also finds that the "difference in complex viscosity" at an oscillation stress greater than 2,000 dyne/cm^2 whereby the present invention undergoes a breaking phenomenon that is not found with a tradition gel made with carbopol is an obvious variation of the prior art. However, it not clear to Applicants how this reasoning is made based on the prior art references as no analysis is provided for this argument based on the prior art. However, what is particularly demonstrative of the nonobviousness of the present invention is that upon application to the skin the present nanogels experience a break down in complex viscosity at which point the nanogels feel wet and refreshing as they are rubbed onto the skin. This phenomenon is not contemplated by any of the cited references alone or combined. Therefore, Applicants assert that the present invention is not obvious in view of the Simonnet, Wiegland and Claudelli references.

Another reference, Kakoki et al. (U.S. Pat. No. 5,162,377; hereinafter "the Kakoki reference") is cited by the Examiner in combination with Simonnet, Wiegland and Claudelli references for rendering Claims 7 to 11, 13, 15, and 16 obvious. According to the Examiner, Simonnet, Claudelli, and Wiegland lack an explicit teaching of the shearing process described in Claims 7 and 8. The Examiner notes, however, that with respect to Claim 16, the Simonnet reference teaches using 1 to 15 percent by weight of a silicone surfactant to form a nanoemulsion. In response to this note, Applicants point out that it is not a silicone surfactant that is used to form a nanoemulsion, but rather, a silicone oil component, and preferably a volatile silicone oil, that is used to form the nanoemulsion. Next, Kakoki fails to teach or suggest a silicone component although it teaches a shearing process for the Kakoki compositions. However, there is no teaching or suggestion in the Kakoki reference to use a shearing process on a composition containing a silicone oil component like that of the present invention. Further, the shearing process of the Kakoki reference is taught to be conducted at least 5 to 10 times to obtain the Kakoki compositions. There is a two step shearing process described in Claim 7 and a three step shearing process in Claim 8 of the present invention. Therefore, the two and three steps that are minimally used with the compositions of the present invention are not taught by the Kakoki reference, and therefore, this reference alone and in combination with the other cited references fails to teach or suggest the present invention.

Because neither the cited references alone nor in combination would lead one of ordinary skill in the art to the compositions of the present invention, as amended, a *prima facie* case of obviousness has not been established. For the reasons stated above, Applicants request that the Examiner's rejection be withdrawn as Claims 1 to 6, and 16 of the present application, as amended, satisfy the requirements of 35 U.S.C. §103(a).

CONCLUSION

In view of the arguments presented above in the present submission, the claims are believed to be in condition for allowance, and issuance of a Notice of Allowance is respectfully solicited.

Respectfully submitted,

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